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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/788,563	02/27/2004	David H. Coy	00537-00900L	9114
26161	7590	06/13/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			TELLER, ROY R	
		ART UNIT		PAPER NUMBER
				1654

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/788,563	COY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 February 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 9-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 9-16, 18-39 and 67-80 is/are allowed.
- 6) Claim(s) 17, 40-66 and 81-89 is/are rejected.
- 7) Claim(s) See Continuation Sheet is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

Continuation of Disposition of Claims: Claims objected to are 11-13,15,16,23-25,27,28,33-35,37,38,42-44,46,47,51-53,55,56,60-62,64,65,69-71,73,74,83-85,87 and 88.

## **DETAILED ACTION**

This office action is in response to the continuation, received 2/27/04.

Claims 1-8 are cancelled.

Claims 9-89 are pending.

### ***Information Disclosure Statement***

The information disclosure statement, received 10/19/04, is acknowledged. A signed copy is enclosed hereto.

### ***Claim Objections***

The specification and claims are objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID NO's to all mentions of specific sequences in the specification and the claims. See 37 CFR 1.821(d).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 40-66, and 81-99 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting tumor growth of small cell lung carcinoma, inhibiting G.I. acid secretion and inhibiting growth release hormone, does not reasonably provide enablement for inhibiting G.I., pancreas, colon, prostate or breast tumors, treating motility disorders of the G.I. tract, suppressing amylase release, treating cancer cachexia, or treating atherosclerosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to methods of inhibiting tumor growth which comprises administering an effective amount of octapeptide bombesin analogs.

The breadth of the claims is excessive with regard to claiming methods of treatment comprising

inhibiting G.I., pancreas, colon, prostate or breast tumors, treating motility disorders of the G.I. tract, suppressing amylase release, treating cancer cachexia, or treating atherosclerosis. Applicant has only provided guidance for methods of inhibiting tumor growth of small cell lung carcinoma, inhibiting G.I. acid secretion and inhibiting growth release hormone. Applicant have provided no guidance of any other methods of treatment as claimed, as evidenced by the absence of working examples of claiming methods of treatment comprising inhibiting G.I., pancreas, colon, prostate or breast tumors, treating motility disorders of the G.I. tract, suppressing amylase release, treating cancer cachexia, or treating atherosclerosis.

In absence of evidence to the contrary, it would not be predictable to the artisan which pathologies could be treated with these peptides

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

### ***Conclusion***

Claims 9-16, 18-39 and 67-80 are allowable. Claims 17, 40-66, and 81-89 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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